

From: Chang, Connie [connie.chang@montana.edu]
Sent: Wednesday, March 18, 2020 11:22 PM
To: Plowright, Raina [raina.plowright@montana.edu]
CC: Martin, Stephen [stephen.martin5@montana.edu]; Walk, Seth [seth.walk@montana.edu]; Bimczok, Diane [diane.bimczok@montana.edu]; Ahmed, Selena [selena.ahmed@montana.edu]; McCalla, Stephanie [stephanie.mccalla@montana.edu]; Blake Wiedenheft [bwiedenheft@gmail.com]; Taylor, Matthew [mptaylor@montana.edu]
Subject: Re: Antibody based test price quote
Attachments: Li_et_al-2020-Journal_of_Medical_Virology.pdf; COVID-19-Science-Report-Diagnostics-13-Mar.pdf

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Hi all,

I did some digging into this. The BioMedomics test appears to be rapid (15 min) and tests for 2 antibodies (IgM and IgG). The sensitivity of the test is 88.66% and specificity is 90.63%. BioMedomics is essentially selling the "Jiangsu Medomics Medical Technologies" kit from China. Attaching the paper this technology is based upon (Li et al).

A better option may be **Aytu BioScience**. In a 113-patient clinical study, the test showed a sensitivity of 87.9% and specificity of 100% percent for IgM antibody detection when compared to RT-PCR, and a 97.2% percent sensitivity and 100% specificity for IgG antibody detection during patients' convalescence period. They are pending FDA emergency testing approval. Same concept, finger prick but faster (2-10 min). Aytu BioScience is selling the "Zhejiang Orient Gene Biotech" kit from China. This kit has received CE Mark and is currently one of the few tests using for CoV screening in China. I can't tell from their website if they have this ready in the US yet. Might be worth giving them a call, but how soon will these be available and shipped to us?

I've attached a pdf from NUS Public Health that lists all tests and highlighted these two so you can compare. Another option is the Wondfo SARS-CoV-2 Antibody Test but I can't find numbers, nor do I think it is being sold here in the US.

I read Florian Krammer's preprint that Raina linked. Although the ELISA assay is great, there are no numbers for sensitivity or specificity from large clinical studies.

I think qPCR is the gold standard. Diane sent me and Steve a long list of different swabs and maybe we want to pursue qPCR testing with whatever swabs/reagents we can best get ahold of? Go forward with Diane's IRB on swab testing and test different types of swabs initially.

Which method (qPCR or IgG/IgM) is ultimately cheaper and faster? How soon can we get the BioMedomics kits?

Best,
Connie

----- Forwarded message -----

From: **Plowright, Raina** <raina.plowright@montana.edu>

Date: Wed, Mar 18, 2020 at 7:39 PM

Subject: Re: Antibody based test price quote

To: Martin, Stephen <stephen.martin5@montana.edu>, Walk, Seth <seth.walk@montana.edu>, Bimczok, Diane <diane.bimczok@montana.edu>, Ahmed, Selena <selena.ahmed@montana.edu>, McCalla, Stephanie <stephanie.mccalla@montana.edu>, Blake Wiedenheft <bwiedenheft@gmail.com>, Chang, Connie <connie.chang@montana.edu>, Taylor, Matthew <mptaylor@montana.edu>

Stephen, do you know the sensitivity and specificity of the test?

A preprint (out today) on new serological test that is sensitive and specific, [here](#). And a [thread](#) explaining the paper on twitter (love it when authors do this!).

I've reached out to colleagues. One person from Einstein med said: "I have been trying to organize a study, but it is very difficult with the intense clinical burden now hitting the system. I would **like to suggest a study where we would try and recruit all healthcare workers to provide a stool sample at the time of viral testing**. If we can get more samples, absolutely. But realistically it will be tough. I would be willing to provide stool collection kits with mail in envelopes all prepaid, etc. if anyone wants to work with us on this." I think this could be a great idea – would have to test general population to estimate prevalence bc health care workers are at high risk of exposure, but HCW may be willing to participate.

I'm going to reach out to some epi colleagues at Yale and Hopkins...must be some big epi studies in progress.

From: "Martin, Stephen" <stephen.martin5@montana.edu>

Date: Wednesday, March 18, 2020 at 3:13 PM

To: "Martin, Stephen" <stephen.martin5@montana.edu>, "Walk, Seth" <seth.walk@montana.edu>, "Bimczok, Diane" <diane.bimczok@montana.edu>, "Ahmed, Selena" <selena.ahmed@montana.edu>, Raina Plowright <raina.plowright@montana.edu>, "McCalla, Stephanie" <stephanie.mccalla@montana.edu>, Blake Wiedenheft <bwiedenheft@gmail.com>, "Chang, Connie" <connie.chang@montana.edu>, "Taylor, Matthew" <mptaylor@montana.edu>
Subject: Antibody based test price quote

Hi All,

I just received a price quote for the Biomedomics Ab test.

\$6.50 per test w/ minimum order of 9k tests = ~\$60k

Please let me know your thoughts on whether this would be a smart purchase and I'll make a recommendation to Alex —> Jason.

SM

On Mar 18, 2020, at 10:14 AM, Martin, Stephen <stephen.martin5@montana.edu> wrote:

Tier 1 - Non-MSU testing through State Lab. This is already in place and happening but appears to be near or at capacity.

Tier 2 - Expanded scale testing. MSU-assisted testing at Bozeman Health in their CLIA-certified lab. We can help personnel at BH get the assays up-and-running and potentially even help process samples, set up reactions, and generate results.

Tier 3 - Moderate scale testing. Samples can be transported directly to the Walk Lab at MSU. I can dedicate a secure BSL2 room containing two laminar flow hoods and an ABI 7500 qPCR machine (very similar to the one named in the CDC SOP).

Tier 4 - Large-scale testing at MSU. We have access to nearly a dozen qPCR machines across campus that could be used if need for capacity reaches this point. Testing on this scale will likely be limited only by the availability of kits/reagents because qualified folks from all over campus have reached out to help, if/when needed, and we will have validated SOPs for them to follow. Kit/reagent availability is a nation-wide problem but there are some work-arounds that could be implemented, such as alternative RNA extraction protocols. If we reach this tier, all molecular biologists interested will be needed to develop innovative approaches. Hopefully, things don't reach this point, but if they do, I'm confident that faculty/staff can make it happen.

On Mar 17, 2020, at 7:24 PM, Martin, Stephen
<stephen.martin5@montana.edu> wrote:

Hi All,

Thank for all being part of the Covid Taskforce Testing Team. There are a lot of emails circulating so I wanted to bring everyone up to date.

Here is where things currently stand regarding testing:

-Seth Walk's lab has the CDC EUA kits which contain primer/probes for nCov_N1 and nCov_N2 as well as the housekeeping RNaseP gene. These kits were obtained from IDT and BioSearch. We are awaiting the nCov_2019 positive control plasmid. When this plasmid

arrives, Seth will begin validating the test and will send out a SOP in the next few days. He is hoping to have the test validated by end of this week or early next week. We're also awaiting RNA extraction kits and one-step RT mixes which will be needed to eventually increase throughput.

-Connie Chang has made a good spreadsheet for campus supplies including an inventory of qPCR machines on campus. Please fill out your labs information if you haven't already. https://docs.google.com/spreadsheets/d/1A0aDzJzXA6JW9A25MyTJlf2YQbfMiNuDvwhOOuD_RYIo/edit#gid=0.

Once the Walk Lab validates the test, we will want to run the test across multiple machines to determine platform variability. Additionally, we will want to compare RNA extraction techniques and RT reagents to optimize methodology.

-Seth will be in communication about how we can assist him. He has some great thoughts about a tiered system of support that he can describe further tomorrow.

-There is a new antibody based test that is close to being released
(<https://www.biomedomics.com/products/infectious-disease/covid-19-rt/>)

[COVID-19 IgM/IgG Rapid Test – BioMedomics Inc.](#)

It can be used for rapid screening of carriers of the virus that are symptomatic or asymptomatic. Recent studies suggest that a high percentage of patients show no clinical symptoms of the virus, thus screening patients is vitally important.

www.biomedomics.com

This could be a game changer for point of care testing, but if you read the FAQ, there are major caveats and it will likely need qPCR confirmation. Thus we need to validate our qPCR tests!

-We are hoping to have a call with the state health lab tomorrow with team leads. We will present our capabilities, and we hope they will provide guidance on what they need. Additionally, we will inquire about potential pathways to making our results 'official'. One potential pathway is to validate the test in-house and then move our equipment to a CLIA certified lab at Bozeman Health. We could then submit an EUA to the FDA to be an official testing center. We will learn more about this on the state call tomorrow and future conversations with Bozeman Health Lab.

-We would like to do a larger testing group call tomorrow before the state call so we can all be on the same page as things are changing so rapidly. Alex has set up a ZOOM for 10am tomorrow and will send an email on this tonight.

Please let me know if you have further questions or want to discuss anything. My # is [REDACTED]

Please forward this email to anyone I missed.

Thanks.

Steve

Stephen Martin, Ph.D.
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